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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,105	12/14/2001	Akikuni Hara	HAG 142	6373

7590 09/17/2004  
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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/017,105

Applicant(s)

HARA ET AL.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/12/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of the invention of Group I (claims 1-11) in the reply filed on July 22, 2004 is acknowledged.

### ***Drawings***

2. The drawings are objected to because boxes 13, 23, 24, 26 and 27 must be labeled with appropriate descriptive text. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because the disclosure is not in proper idiomatic English. Examples of such language include, "...in respect of trunk areas of an uneven human body," (page 2, lines 11 and 12), "...and further it is difficult to measure suppressing human body minute movement," (page 11, lines 9 and 10), "...the optimal dose taking account of human body safety is controlled and obtained as follows," (page 24, lines 2 and 3), etc..

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Appropriate correction is required.

***Claim Objections***

4. Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only refer back to claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, reference to "...the middle point..." lacks antecedent basis. The scope of the claim is unclear because it is uncertain whether or not the applicants intended to set forth a booster coil. The examiner will assume that a booster coil was intended to be recited in any rejection on the merits.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara (Pat. No. 4,094,322).

Regarding claims 1-3, Hara discloses an electric potential therapy apparatus comprising an electric potential treatment device provided with a main electrode 3, an opposed electrode 27, a high voltage generation apparatus 16 for applying a high voltage to the respective electrodes, an induced current control means (either voltage

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regulator 20 or electrode spacing adjustment elements 54 and 55), and a power source (see Fig. 7) for driving the high voltage generation apparatus.

Regarding claim 5, the laws of nature dictate the particular equation describing the intensity of the surface electric field at respective areas of a human body –not the applicants' apparatus. The relationship is what it is and exists regardless of whether or not it is measured. A related comment applies to claim 7.

The functional language of claim 6 was considered, but deemed insufficient to saliently distinguish over the apparatus of the prior art. The applicants are not claiming a method of measuring current flow, but an electric potential apparatus.

A similar comment applies to claim 8. The apparatus of the Hara patent is capable of performing the functional language recited, merely dependent upon the electrode spacing and the setting of the voltage regulator.

Likewise in claim 10, attempts to distinguish the invention over the apparatus of the prior art by alluding to the relative distance between a human body and an electrode will be considered insufficient in overcoming the art of record. The spacing that results in a 10.0 mA/m<sup>2</sup> current density respective to various areas of the body can vary widely dependent upon a number of factors including voltage regulator setting, impedance of the patient under treatment, patient size, electrode area, etc.

The limitations set forth in claim 11 are clearly anticipated.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hara (Pat. No. 4,094,322) in view of Hara et al. (Pat. No. 4,802,470).

Hara does not explicitly show a grounded middle point of a booster coil. Hara et al., however, disclose a substantially similar apparatus wherein a variety of different coil arrangements are shown including a center tapped secondary coil employed to output high voltage to therapeutical electrodes (see for example Fig. 2A). The use of "grounded middle points" in transformers is old and well known by those of ordinary skill in the electronics arts and represents convenient way to pick-off equal voltages from the secondary. Hara et al. teach that such a configuration allows for a high potential between electrodes, while permitting each electrode to individually handle smaller voltages and thus enable "...low withstand voltage to ground," (col. 1, lines 35-47). To employ a grounded middle point booster coil in the system of Hara would have therefore been considered obvious by those of ordinary skill in the art looking to take advantage of the above benefits.

### **Conclusion**

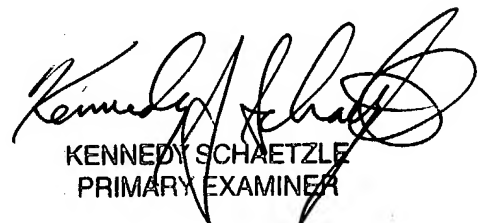
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaezle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
September 15, 2004

  
KENNEDY SCHAEZLE  
PRIMARY EXAMINER